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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,094	09/12/2003	Kirsty Jane Dodgson	875.092US1	7668

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,094	DODGSON, KIRSTY JANE	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *2-7,10-14,20-22,24 and 26-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,9,15-19,23 and 25* is/are rejected.

7)☒ Claim(s) *19+23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2006 has been entered.

Amendment Entry

2. The amendment filed September 11, 2006 has been entered. Claims 1 and 8-9 have been amended. Claims 2-7,10-14, 20-22, 24 and 26-43 have been withdrawn from consideration. Claims 1, 8-9, 15-19, 23 and 25 are under consideration in this office action.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 1, 8-9, 15 and 25 under 35 U.S.C. 102(b) as being anticipated by Arthur et al., (US Patent 5,871,910); and

b) The rejection of claims 1, 8-9, 15, 17-19, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergeron et al., (US Patent 5,994,066).

Response to Arguments

4. Applicant's arguments filed September 11, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The written description rejection of claims 1, 8-9, 15-19, 23 and 25 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record. The rejection was on the grounds that the instant specification and claims are encompassing unidentified portions of the sequences substantially corresponding to the complements or portions thereof for SEQ ID NO: 2, 3 and 4.

Applicants' state that because *vanA* sequences and specific probes and primers are well known, that there is no need for further teachings and the rejection should be withdrawn. Portions refer to subsequences within SEQ ID NO:2, 3 and 4 and not to the full-length sequences. There is no disclosure of what sequence substantially corresponds to the complement. Thus there is no evidence of record that portions of the claimed nucleotides were in applicants' possession at the time of filing. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the substantially

corresponding complement or portions thereof. The written description in this case only sets forth specific nucleotide sequences in SEQ ID NO:2-4, therefore the written description is not commensurate in scope with the claims drawn to substantially corresponding complements or portions of SEQ ID NO:2-4.

Applicants' urge that because high stringency conditions recited, there would be a common structure and function among the *vanA* specific probes, therefore the rejection should be withdrawn. However, applicants have not pointed to how to define complements or the portions, thus there is no written description support for determining the common core or structure. Neither has applicant pointed to any guidance as to what the portions are; or what portions can or cannot be used in the method of detection being claimed. Furthermore, applicants have not disclosed a sequence that substantially corresponds to SEQ ID NO:2-4. There is no requirement for the full-length complement. There is no teaching whether these substantially corresponding sequences includes deletions, additions or substitutions. There is no description of how much correspondence there must be. The specification does not include structural examples of sequences that substantially correspond to portions thereof. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d

at 1012, 10 USPQ2d at 1618. Here there are no representative examples of portions thereof. Therefore applicants' assertions are not persuasive.

Thus, with the exception of specifically named nucleotide sequences, the skilled artisan cannot envision the detailed structure of the portions thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph and the rejection is maintained.

6. The rejection of claims 1, 8-9, 15-19, 23 and 25 under 35 U.S.C. 112, second paragraph.

It appears that applicants believe that the amendments overcome the rejection, however some of the rejections are being maintained.

a) The rejection is on the grounds that the phrase "substantially corresponding to" or "corresponding to" with respect to the sequences in the claims are relative terms which render the claims indefinite. The phrases are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There are no requisite requirements regarding the how to determine whether a sequence substantially corresponds. It is unclear how much correspondence there must be or what different level of correspondence is required to meet substantial

correspondence. Therefore the metes and bounds of the phrase cannot be ascertained. Thus, clarification is required to overcome the rejection.

b) Despite the amendments, claim 1 is still indefinite. The term "high stringency hybridization conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, one cannot determine the metes and bounds of the claim language, therefore the term is indefinite. The term high stringency hybridization conditions is a term of degree and based upon parameters that are not defined in the specification or the claims. The specification teaches that stringent conditions are sequence-dependant and will be different in different circumstances in order to maximize the differences in stability. As such, the term is dependant upon specific conditions that are not recited in the claims and specification fails to define the metes and bounds of the phrase. Therefore one skilled in the art would not be readily apprised as to the metes and bounds of the high stringency hybridization conditions. Therefore, a recitation of the specific conditions is suggested as a means for overcoming the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The rejection of claims 1, 15-18, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by Petrich et al., (Mol. and Cellular Probes, 1999, Vol. 13:275-281) is maintained for reasons of record.

The rejection was on the grounds that Petrich et al., teach a method to detect *vanA* in a sample, comprising: a) contacting a physiological or peri-rectal sample suspected of comprising amplified *vanA* nucleic acid with at least one *vanA* -specific oligonucleotide probe under high stringency hybridization conditions effective to form a hybrid between the *vanA* -specific oligonucleotide probe and *vanA* nucleic acid in the sample, wherein the *vanA* -specific oligonucleotide probe under high stringency conditions hybridizes to sequences which include sequences substantially corresponding to SEQ ID NO:3, the complement thereof, or a portion thereof and comprises sequences which include sequences substantially corresponding to SEQ ID NO:3, the complement thereof, or a portion thereof, and wherein the amplified *vanA* nucleic acid has sequences substantially corresponding to SEQ ID NO:2, the complement thereof, or a portion thereof and sequences substantially corresponding to SEQ ID NO:4, the complement thereof, or a portion thereof; probes which are not specific for *vanA*-specific probe and are *vanB* specific probe and b) detecting or determining the presence or amount of hybrid formation.

Applicants' urge that Petrich et al., do not disclose a *vanA* specific probes that hybridizes under high stringency conditions and includes sequences substantially corresponding to SEQ ID NO:3, the complement or a portion thereof. However the claims encompass probe sequences that do not require the full-length of SEQ ID NO:3

or even the full length of the complement, rather the claims merely require an undefined portion, which encompasses any portion or fragment of SEQ ID NO:3 or the complement. Petrich et al., teach specific oligonucleotides probes for *vanA* wherein these probes comprise a portion of SEQ ID NO:3. The claims simply require a portion of the sequences substantially corresponding to SEQ ID NO:2, 3 and 4. Since the portion is not defined and Petrich et al., teach a portion of nucleotides capable of hybridizing, the art meets the limitations of the claims. The fact that Petrich et al., disclose that these probes were derived from different regions within the *vanA* gene is irrelevant since several of the same nucleotides are recited in those sequences.

Applicants' urge that the claims require high stringency. However the it is well known in the art that high stringency refers to the strength of the bonds between the bases and does not equate to a level of sequence identity between the strands. Therefore applicants' arguments are not persuasive and the rejection is maintained since, Petrich et al., teach a method to detect *vanA* in a sample just as required by the claims.

Applicants' argue that Petrich et al., do not disclose a *vanA* specific probes that includes sequences substantially corresponding to SEQ ID NO:3, the complement or a portion thereof. However the claims do not require hybridization specifically to the full length of SEQ ID NO:2-4 or their complement, rather the claims require hybridization to a sequence which comprises any portion thereof, thus the art meets the recited limitations due to the open language of the claims. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

8. The rejection of claims 1, 8-9, 15-19, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by Modrusan (US Patent 6,274,316) for reasons already of record.

The rejection was on the grounds that Modrusan teaches a method to detect *vanA* in a sample teach a method to detect *vanA* in a sample, comprising: a) contacting a physiological or peri-rectal sample suspected of comprising amplified *vanA* nucleic acid with at least one *vanA* -specific oligonucleotide probe under high stringency hybridization conditions effective to form a hybrid between the *vanA* -specific oligonucleotide probe and *vanA* nucleic acid in the sample, wherein the *vanA* -specific oligonucleotide probe under high stringency conditions hybridizes to sequences which include sequences substantially corresponding to SEQ ID NO:3, the complement thereof, or a portion thereof and comprises sequences which include sequences substantially corresponding to SEQ ID NO:3, the complement thereof, or a portion thereof, and wherein the amplified *vanA* nucleic acid has sequences substantially corresponding to SEQ ID NO:2, the complement thereof, or a portion thereof and sequences substantially corresponding to SEQ ID NO:4, the complement thereof, or a portion thereof; probes which are not specific for *vanA*-specific probe and are *vanB* specific probes and b) detecting or determining the presence or amount of hybrid formation.

Applicants' urge that Modrusan discloses probes created from different regions of the *vanA* gene and does not teach a *vanA* specific probes that includes sequences substantially corresponding to SEQ ID NO:3, the complement or a portion thereof. However as previously discussed the claims encompass probe sequences that do not

require the full-length of SEQ ID NO:3, rather the claims merely require a portion thereof. There is no limitation on the size or number of nucleotides within the claimed portion, therefore any nucleotides in common meet the portion thereof limitation. The fact that Modrusan discloses probes derived from different regions within the *vanA* gene is irrelevant since several of the same nucleotides are recited in those sequences and meet the portion thereof limitation.

New Grounds of Objection and Rejection

Claim Objections

9. Claim 15 is objected to because of the following informalities: Claim 15 fails to recite which claim it is dependent upon. Appropriate correction is required.

10. Claims 19 and 23 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for an the *vanA* specific oligonucleotide probe that is no more than 50 nucleotides in length and has at least 10 contiguous nucleotides of SEQ ID NO:3 or the complement thereof.

Applicant did not point to support in the specification for the *vanA* specific oligonucleotide probe that is no more than 50 nucleotides in length and has at least 10 contiguous nucleotides of SEQ ID NO:3 or the complement thereof. Moreover, applicants failed to specifically point to the identity or provide structural characteristics of the instantly claimed *vanA* specific oligonucleotide probe. Thus, there appears to be no teaching of the *vanA* specific oligonucleotide probe that is no more than 50 nucleotides in length and has at least 10 contiguous nucleotides of SEQ ID NO:3 or the complement thereof. The specification beginning at page 19, lines 24 states that while oligonucleotides probes of different lengths and base composition may be used for detecting the *vanA* gene or the *vanB* gene, preferred oligonucleotides have lengths from 15 up to 40 nucleotides and are sufficiently homologous to the target nucleic acid to permit amplification of a *vanA* or *vanB* template and/or hybridization to such a template under high stringency conditions. Thus it appears that the entire specification appears to fail to recite support for the newly *vanA* specific oligonucleotide probe. Therefore, applicants must specifically point to page and line number support for the identity of the *vanA* specific oligonucleotide probe that is no more than 50 nucleotides in length and has at least 10 contiguous nucleotides of SEQ ID NO:3 or the complement thereof.

Accordingly, the claim incorporates new matter and is rejected.

Conclusion

12. No claims allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 17, 2007